

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125510/0.0
Review Office	OVRR
Applicant	Novartis Vaccines and Diagnostics, Inc. / Lic. # 1751
Product	Influenza Vaccine, Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	04-SEP-2015 05:34 PM
Author	GARNETT, THEODORE
Outside Phone Number	617-871-8384
FDA Originated?	Yes
Communication Categories	IR – Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Questions regarding test data for the monovalent bulks, reference agents used for testing, and a key to indicate/describe the test material
FDA Participants	Brenda Baldwin
Applicant Participants	Mayuresh Gadre

Telecon Body:

The following questions were conveyed to the firm during the telecon:

1. CBER requested the test data for the monovalent bulk ASAP (Tuesday, September 8, 2015), and understands that the trivalent bulk test data will be available by the end of September.
2. CBER asked NVD to clarify what reference agents they used during testing.

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3. CBER requested a key to indicate/describe the test materials NVD sent to them.